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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/736,266	12/15/2003	Michael John Rutter	CHM-009	3842

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HASSE & NESBITT LLC
7550 CENTRAL PARK BLVD.,
MASON, OH 45040

EXAMINER	
DIXON, ANNETTE FREDRICKA	
ART UNIT	**PAPER NUMBER**
3743	

DATE MAILED: 03/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/736,266	RUTTER, MICHAEL JOHN	
	Examiner	Art Unit	
	Annette F. Dixon	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *1/13/2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. The amendment filed on January 13, 2006, has been entered. Examiner acknowledges that **Claims 1-25** are pending in this application, with **Claims 21 and 23** having been amended.

2. Applicant's arguments filed January 13, 2006, have been fully considered but they are not persuasive. Regarding Applicant's argument of Depel (US 4,582,058), Applicant's claims do not recite the limitation of the "opening of a second valve during pressures associated ***with speaking***." (Emphasis Added) Furthermore, as stated by the previous Examiner, the "second valve may be predeterminely tuned." Finally, the device of Depel is fully capable of performing and thus denotes anticipation under 35 USC §102(b) rejection.

3. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the "speaking aspect") are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Further, Applicant is reminded recitations of intended use utilizing functional language may not be given patentable weight in apparatus claims. While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function alone. Please see MPEP §2114.

4. Applicant's arguments with respect to **Claims 21-25** have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102 and 35 USC § 103

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. **Claims 1-20** are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Depel et al (US 4,582,058).

9. **As to claims 1-20**, Depel et al teaches a tracheotomy valve unit adapted to cooperate with a tracheotomy tube inserted into a patient's trachea said valve unit

comprising: (a) a first end adapted for connection to the free end of the tracheotomy tube; (b) a second end comprising a valve unit inlet; (c) a first valve **1** that permits airflow from the valve unit inlet through the valve unit and to the tube in the patient's trachea when the patient inhales, and blocks airflow from the tube through the valve unit when the patient exhales, said first valve comprising a seating ring **8**, a thin, flexible diaphragm **7** biased against the seating ring, thereby making positive closure contact therewith, and a rivet **9** for connecting the diaphragm to the seating ring, the rivet having a length to bias the diaphragm against the seating ring; and (d) a second valve **(See Col. 6, lines 63-68 and Col. 7)** that permits airflow from the tube through the valve unit and out the valve unit when the intrathoracic pressure during expiration is greater than about 12 cm of water, and blocks such aiirtlow when the intrathoracic pressure during expiration is less about 3 cm of water, wherein the second valve comprises a slit valve or an umbrella valve that is located in an axial bore hole of the rivet (**See Cols. 3-10; See Col. 9 lines 33-57 which inherently teaches the pressure recited above**). It should be noted in Col. 5, lines 38-45, Depel teaches that the blow-out/second valve may be predeterminely tuned, i.e., the valve may be set at a certain pressure at which to open and close which is what Applicant has disclosed on the specification on page 4, paragraph 20. Therefore, it would have been obvious, if not inherent, to one of ordinary skill in the art to provide the second valve opening and closing at a certain pressure based on the intended use of the valve.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. **Claims 21-25** are rejected under 35 U.S.C. 103(a) as being unpatentable over Lurie (6,604,523).

13. **In regards to Claim 21, 23, and 24,** Lurie discloses a tracheotomy valve unit adapted to cooperate with a tracheotomy tube inserted into a patient's trachea. The valve unit comprising: a first end (138) adapted for connection to the free end of the tracheotomy tube; a second end (134) comprising a valve unit inlet; a first valve (160) that permits airflow from the valve unit inlet through the valve unit and to the tube in the patient's trachea when the patient inhales and blocks airflow from the tube through the valve unit when the patient exhales, said first valve comprising a seating ring (the cylindrical shape region 144 where the diaphragm is resting), a thin, flexible diaphragm (148) biased against the seating ring, thereby making positive closure contact therewith, and a rivet (150) having a length to bias the diaphragm against the seating ring; and a

second valve (140) that begins to open to permit airflow from the tube through the valve unit and out the valve unit when the intrathoracic pressure during expiration is greater than about 3 cm of water, is fully opened when the intrathoracic pressure reaches about 12 cm of water, and blocks such airflow when the intrathoracic pressure during expiration is less than about 3 cm of water, wherein the second valve comprises a slit valve or an umbrella valve that is located in an axial bore hole of the rivet.

14. Regarding the adaptation of the valve unit to cooperate with a tracheotomy tube, "the endotracheal tube or like device is for insertion into the patient's airway and provides a convenient attachment for the valving system to the patient" (Please see Column 5, Lines 45-51).

15. Regarding the limitations associated with the first valve (160), the tracheotomy valve unit of Lurie is designed to provide respiratory air to a patient while permitting expiratory gas to exit via the second valve. In addition, the diaphragm, seating ring, and rivet are all disclosed in Figure 16A and Column 21, Lines 1-5 and 15-30.

16. Regarding the limitations associated with the second valve (140), the tracheotomy valve unit of Lurie can be modified to impeded air from leaving the patients lungs until a positive intrathoracic pressure range of about 2 cm of water to about 20 cm of water can be reached. (Please see Column 11, Lines 22-37). Furthermore, the first valve (160) will remain closed until as the first valve is set to open when the negative intrathoracic pressure is in the range of about -3 cm of water to –30 cm of water. (Please see Column 10, Line 63 thru Column 11, Line 2). Finally, both valves are regulated via the positive or negative nature of the intrathoracic pressure. During

inspiration (negative intrathoracic pressure), the first valve (160) will open, while the second valve (140) will be closed; in contrast, during expiration, the first valve (160) will be closed, while the second valve (140) will be open.

17. Lurie teaches a tracheotomy valve unit comprising all limitations recited in **Claim 21,** but does not expressly disclose the use of a silt or umbrella valve and the operation ranges of intrathoracic pressure. Regarding the silt or umbrella valve, Applicant has not asserted that the specific valves recited provides a particular advantage, solves a stated problem, or serves a particular purpose different from that of providing a means for blocking and permitting airflow, thus the use of the silt or umbrella valve lacks critically in its design. Regarding the operation ranges of intrathoracic pressure, Applicant has not asserted that the specific range values recited provides a particular advantage, solves a stated problem or serves a purpose different from that of insuring that during expiration (positive intrathoracic pressure) the second valve begins to or in the extreme becomes fully open, while during inspiration (negative intrathoracic pressure) the second valve blocks airflow; thus, the use of the range of intrathoracic pressures lacks criticality in its utilization. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with a multitude of valves and operation ranges. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify apparatus of Lurie to satisfy the valve and operational requirements.

18. **In regards to Claim 22,** Lurie discloses the diaphragm is made of a low modulus silicone sheet material. (Please see Column 11, Lines 33-34).

19. Further, it should be noted that the portion of the recitation that claims the diaphragm is made of a low-modulus silicone sheet material is directed to a process. Since the claim is an apparatus/product claim, patentable weight is only given to the end product. "Even though product-by process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by process claim is in the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted).

20. **In regards to Claim 25,** Lurie teaches the second valve to allow for increasing airflow through it as the intrathoracic pressure during expiration increases beyond 4 cm of water, yet fails to disclose a modification in the second valve when a maximum airflow is achieved at a pressure of 10 cm of water. However, the very essence of Lurie's tracheotomy valve unit is for providing cardiopulmonary circulation to a patient. Because of this, the device inherently has a maximum airflow pressure and would not be allowed by the rescuer to exceed intrathoracic pressures that would be harmful to the patient. Furthermore, as well known in the art, pressure-responsive valves are designed to function and be modified to perform in a variety of operating ranges. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of Lurie by adding a maximum pressure shut off to the second valve for the purpose of insuring patient safety.

Conclusion

21. The prior art made of record but not expressly relied upon is considered pertinent to Applicant's disclosure. The balance of art listed by US Patent Number below, shows additional inventions in the field of devices capable of operating as a tracheotomy valve unit.

Lurie (6986349), Evans (4697593), and Barkalow (4326507)

22. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Annette F. Dixon whose telephone number is (571) 272-3392. The examiner can normally be reached on Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Annette F Dixon
Examiner
Art Unit 3743
March 8, 2006

Henry Bennett
Supervisory Patent Examiner
Group 3700